

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12506



2 - LABEL SAMPLE

000001

1. FLAG SURVEILLANCE <input type="checkbox"/> COMPLIANCE <input type="checkbox"/>				2. SAMPLE		3. SAMPLE NUMBER 97 730-162	
4. CP NO. 2128593		5. DATE COLLECTED 8/29/97		6. PRODUCT CODE 60CEB21		7. <input checked="" type="checkbox"/> FIRM	
10. RELATED SPL n/a		11. PC 2		13. SPLING DIST DAL		8. PROGRAM ASSIGN CODE 1. 63R800 2. 3.	
		12. COLL NO. 521		14. COLL DIST DAL		9. HOURS 1. 6 2. 3.	
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) Product is a white colored hard-gelatin capsule, packaged in plastic bottle with a blue screw-cap lid. The bottle is labeled with a colored, printed, stick-on paper label which reads in part, "ESCALATION TM *** THE ORIGINAL ALL NATURAL *** ENERGIZING DIETARY SUPPLEMENT *** WITH THERMOGENIC PROPERTIES *** NO. 821 P.S.E. SE *** 60 CAPSULES *** ENZYMA THERAPY *** EACH CAPSULE CONTAINS: COLA NUT EXTRACT (COLA NITIDA) *** 250MG *** GREEN TEA EXTRACT *** (CAMELLIA SINENSIS) *** 250MG *** HUANG EXTRACT *** (EPHEDRA SINENSIS) *** 250MG *** MANUFACTURED EXCLUSIVELY BY *** ENZYMA THERAPY, GREEN BAY, WISCONSIN 54311 *** DIRECTIONS: *** WARNINGS: *** Sealed by M.B. and labeled "OC 97-318 "a" in Bag"							
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) HQ request. Analyze for ephedra and caffeine.						17. MFG CODES (Labels, pkg, shipping containers) 035X46QG	
18. MANUFACTURER (Name, address & ZIP) Enzymatic Therapy, Inc. 825 Challenger Dr. Green Bay Wisconsin 54305				19. SHIPPER (Name, address & ZIP) unknown		20. DEALER (Name, address, ZIP & telephone) collected from <div style="background-color: black; width: 100px; height: 50px;"></div>	
21. SIZE OF LOT FROM WHICH SAMPLED n/a				22. EST VALUE unknown		23. RECEIPT ISSUED FDA472 <input type="checkbox"/> FDA484 <input type="checkbox"/> NONE <input type="checkbox"/>	
						24. DATE SHIPPED & DOC REF 8/29/97	
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) Sample was collected from the [redacted] Office on the morning of 8/29/97. Sample consists of the previously opened portion of a bottle found in the vicinity of a woman who later died. SEE REMARKS							
26. HOW PREPARED Sample was collected as sealed by the [redacted]'s office, transported to the [redacted] where ID'd as in block 27, placed in paper bag, and sealed as in block 28. Sample shipped 8/29/97							
27. COLL IDENT ON PKG AND/OR LABEL 97-730-162 8/29/97 KRL				28. COLLECTOR'S IDENTIFICATION SEAL 97-730-162 8/29/97 Kara R. Lenons, Investigator			
29. SAMPLE DELIVERED TO Federal Express				30. DATE DELIVERED 8/29/97		31. LAB SEA	
				32. LAB W/SPLIT SAMPLE n/a		33. ORIG C/R & RECORDS TO DAL	
34. RCDS OBTAINED	a. INVOICE NO. AND DATE SEE RMKS				b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE SEE RMKS		
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE SEE RMKS						
35. REMARKS (If additional space is needed, attach Form FDA 464a, C/R Continuation Sheet) Please refer to attached memo and banyan message. The medical examiner requests a copy of the analysis report be sent to: DR. [redacted]. Autopsy and pathology reports can be obtained [redacted] in approx. 2-3 weeks, but must be authorized by Judge [redacted].							
36. CONSUMER COMPLAINT NO. OR RECALL NO. n/a		37. AMT. \$ CRED. CO. <input type="checkbox"/> n/a <input type="checkbox"/> C <input type="checkbox"/> V <input type="checkbox"/> B <input type="checkbox"/>		38. 704(d) SPL YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		39. COLLECTOR (Typed name and signature) Kara R. Lenons	

FORM FDA 484 (11/86) PREVIOUS EDITIONS MAY BE USED.

COLLECTION REPORT

SAMPLE RECORD COPY 4

000002

1 PRODUCT Escalation Capsules		2 SAMPLE NO 97-730-162	
3a SAMPLE CLASSIFICATION		b LABORATORY CONCLUSIONS Sample consisted of hard gelatin capsules. Analysis by HPLC found: (61.6 mg/g) 47.3 mg/capsule caffeine or 94.6% declared. A trace of theobromine and no theophylline was detected. (16.2 mg/g) 12.5 mg/capsule ephedrine and a trace of trace of pseudoephedrine was found or 83.3% declared total alkaloid.	
CODE	PAC NO		
4	63R800		
c NAME AND TITLE Janet L. Burke, Chemist		d SIGNATURE <i>Janet L. Burke</i>	DATE 9/5/97
4a DISTRICT CONCLUSIONS			
b NAME AND TITLE		c SIGNATURE	d DATE

FORM FD 465 (4/78)

SAMPLE SUMMARY

12506

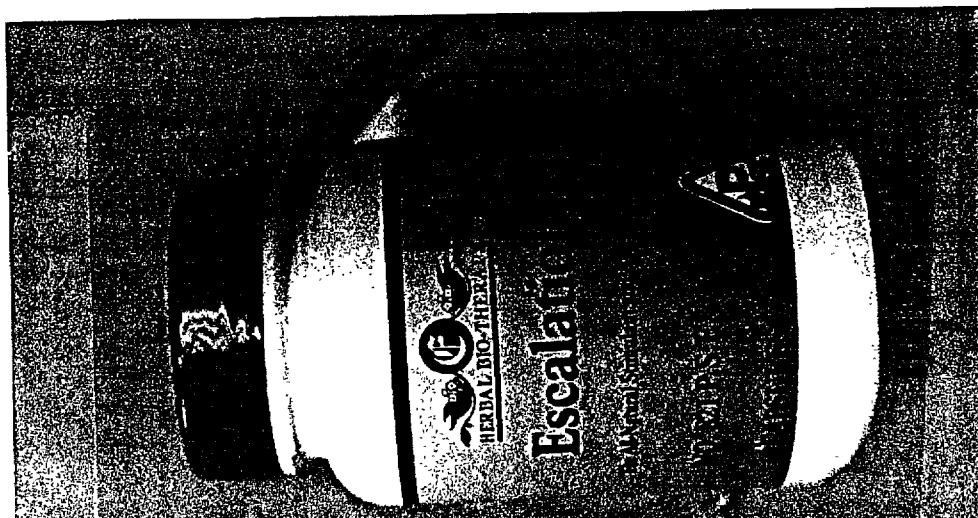
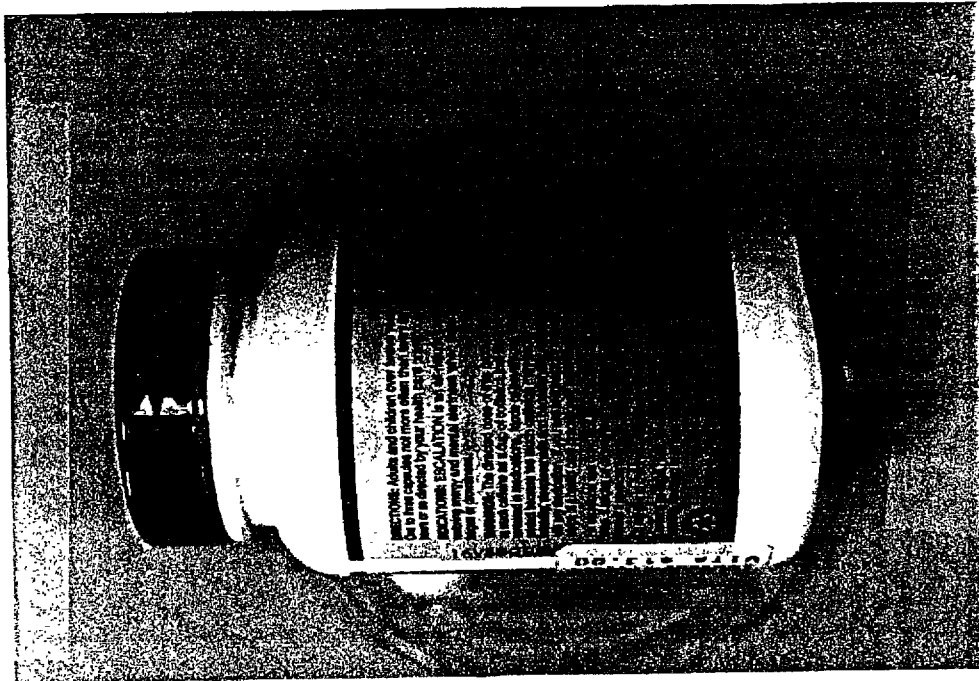
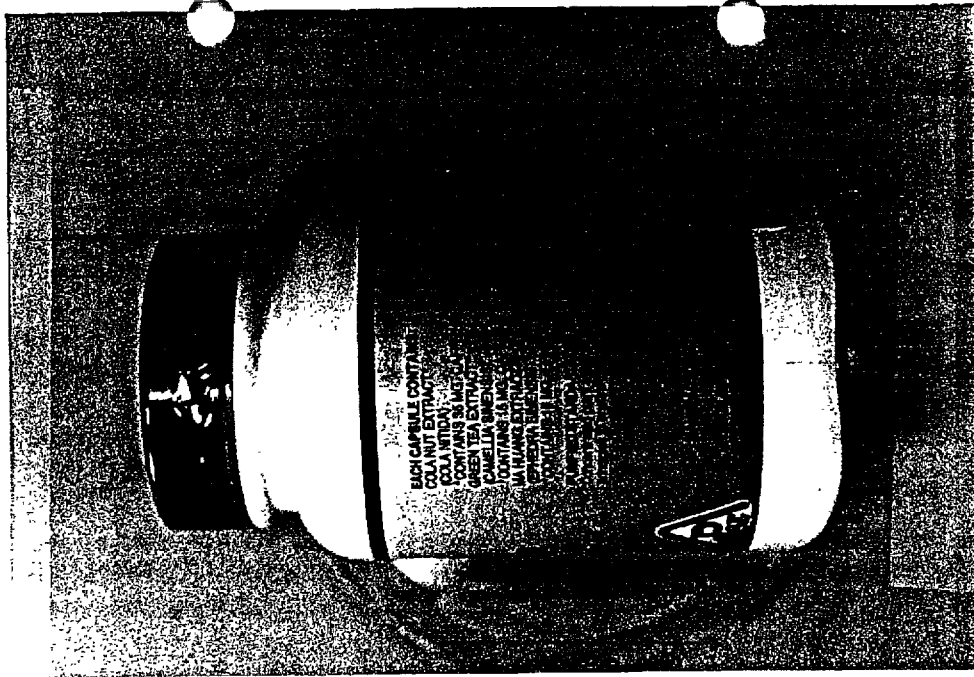
97 SEP -9 A9:06

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN IFS-452

000003



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000004

FATIGUE

Herbal Surge™ • Escalation™

What would you do if you had more energy?

With enough energy, you could keep your eyes open at morning meetings. You could stick with projects from start to finish. After work, you could hit the gym, pick up groceries, cook supper, play with your children, and sit down with your calculator to solve our country's budget crisis.

Okay, maybe your wealth of energy won't end the national deficit. But it will help you do the things you want to do. If fatigue is keeping you from living your life to the fullest, take advantage of natural products that will unlock your inner vitality.

Herbal Surge™, No. 2075 Guaranteed energy boost

Lehning Laboratories' Herbal Surge™ is a homeopathic remedy that relieves fatigue due to hard work, physical activities, and minor illness. Herbal Surge works with your body to give

"Herbal Surge is remarkably effective in elevating energy levels, even in severe cases of fatigue."

you a natural lift you can feel immediately. It helps you sustain peak energy levels throughout the day, without any side effects.

Herbal Surge includes natural compounds such as,

- *Avena sativa* 1x—Relieves minor debility.

- *Podophyllum peltatum* 3x—Alleviates fatigue.

- *Rhamnus frangula* 2x—Relieves general weariness

Michael T. Murray, N.D., Enzymatic Therapy's Director of Research, says, "Herbal Surge is remarkably effective in elevating energy levels, even in severe cases of fatigue."

When you try Herbal Surge, you'll find that it effectively and gently restores your natural vitality.

Escalation™, No. 821 P.S.E. Energy to burn

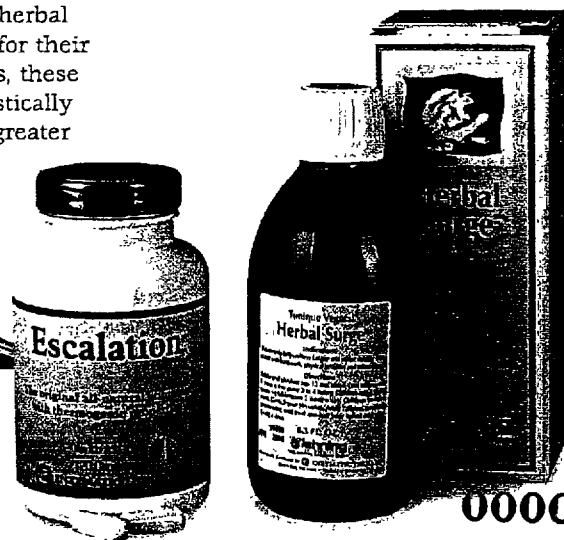
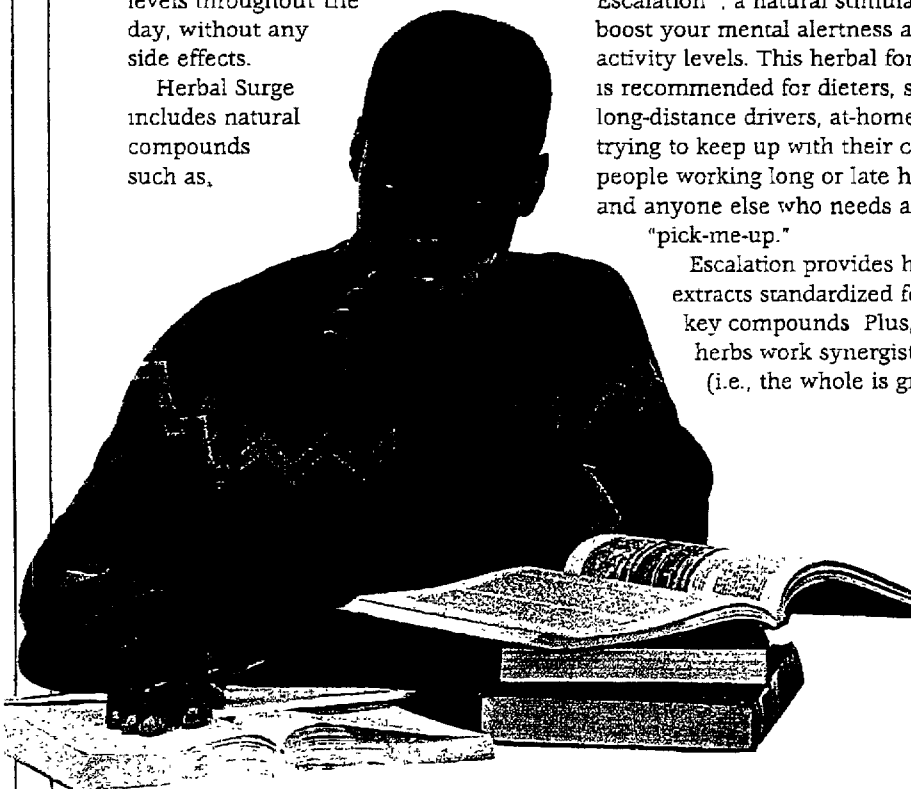
Escalation™, a natural stimulant, will boost your mental alertness and activity levels. This herbal formula is recommended for dieters, students, long-distance drivers, at-home parents trying to keep up with their children, people working long or late hours, and anyone else who needs a quick "pick-me-up."

Escalation provides herbal extracts standardized for their key compounds. Plus, these herbs work synergistically (i.e., the whole is greater

than the sum of its parts), so you get maximum value and an energy lift you can count on.

Escalation is especially popular among dieters because it helps them maintain high activity levels as they reduce their calorie intake. In fact, Escalation has always been one of our top-selling products.

"I have found Escalation to be of particular value in helping me maintain a high energy level during my workouts without any 'jag' or 'wired' feeling. Escalation allows me to achieve my natural peak potential without a 'letdown' or feeling of fatigue after the product has run its course. It is an excellent product."



000005